

Remarks

Claims 52-75 are pending in the subject application. By this Amendment, Applicants have canceled claim 66 and amended claims 52-54, 59, 61, 63, 65, 70, 73 and 74 to correct typographical errors and attend to other issues. Support for the amendments can be found throughout the subject specification, including the originally pending claims in the PCT application and the previously presented claims. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 52-65 and 67-75 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 1, part (g) and 61 have been objected to because of informalities. Applicants note that claim 1 has been canceled and have assumed that the claim objected to is claim 51. In accordance with the Examiner's suggestion, claims 51 and 61 have been amended, as well as claims 59 and 63 which contained the same inadvertent errors. Accordingly, reconsideration and withdrawal of the objections is respectfully requested.

Claims 52-75 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action indicates that the specification is enabled for the CXCL11 antagonists represented by the polypeptide sequences of SEQ ID NOs: 3-5 but is not enabled for any other isolated antagonists of CXCL11. The Office Action also argues that the breadth of the claims is excessive because the claims read on mutant CXCL11 polypeptides comprising substitutions in the recited residues, but also potentially in any other residue within the CXCL11 polypeptide. The Office Action also argues that the specification provides guidance showing only the polypeptides of SEQ ID NOs: 3-5, but does not provide guidance or examples of any other polypeptide that can function as a CXCL11 antagonist, or teach which additional residues can be substituted and still retain antagonist function. Finally, due to the unpredictability inherent in mutating amino acids within a given protein, a person of ordinary skill in the art would not predict how to make and use any CXCL11 antagonist other than those of SEQ ID NOs: 3-5 without further, undue experimentation. Applicants respectfully assert that the claims as filed are enabled and that the Office Action has improperly interpreted and rejected the claims presented for examination.

Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention (*Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592,

599 (Fed. Cir. 1983)) and is not precluded even if some experimentation is necessary. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984); *W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Applicants also submit that nothing more than objective enablement is required, and therefore, it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Additionally, the Patent and Trademark Office Board of Patent Appeals and Interferences has stated: “The test [for enablement] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed”. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982); *see also Ex parte Erlich* 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be “tedious and laborious,” such experimentation is nevertheless “routine” defining “routine” experiments as those which use known methods in combination with the variables taught in the patent to achieve the expected, specific, patented result).

Applicants first address the argument that the scope of claims is excessive because the claims not only read on mutant CXCL11 polypeptides comprising amino acid substitutions in the recited residues, but also on mutant CXCL11 polypeptides containing amino acid substitutions in, potentially, any other residue within the CXCL11 polypeptide. In this regard, Applicants notes that the claims recite certain specified amino acid substitutions within the sequence of human CXCL11. Thus, it is respectfully submitted that the claims do not read on mutant CXCL11 polypeptides containing amino acid substitutions in, potentially, any residue within the CXCL11 polypeptide; rather, the claims read on mutant human CXCL11 polypeptides that contain certain specified amino acid substitutions within the sequence of human CXCL11.

Turning to the argument that the specification provides guidance showing only the polypeptides of SEQ ID NOs: 3-5, but does not provide guidance or examples of any other polypeptide that can function as a CXCL11 antagonist, or teach which additional residues can be substituted and still retain antagonist function, Applicants respectfully submit that the as-filed specification enables the claims currently pending in this matter. As noted above, all that is

necessary is that the as-filed specification enable one skilled in the art to make and use the claimed invention. As stated by the Board of Appeals, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. In this regard, Applicants note that the claims recite specific amino acid substitutions within the claimed CXCL11 polypeptide and the as-filed specification provides adequate guidance as to the direction in which any experimentation should proceed to identify polypeptides within the scope of the claimed invention (see, for example, Examples 1-3 of the as-filed specification). Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, reading "Frank C. Eisenschenk". The signature is fluid and cursive, with the first name "Frank" and last name "Eisenschenk" clearly legible.

Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950  
Gainesville, FL 32614-2950

FCE/jb/sl